

REMARKS

Claim 8 has been amended as shown above. These amendments consist of solely of deletion of optional substituents from the scope of the claimed composition. Support for these amendments can be found throughout the specification including, for example, at page 6, line 9 - page 9, line 21 and in original claims 1, 8, and 12. These disclosures teach that the deleted substituents are optional in the claimed compositions.

Given this disclosure, Applicants may disclaim these optional substituents without violating the prohibition against introduction of new matter. See *In re Johnson*, 558 F.2d 1008, 1019 (C.C.P.A. 1977) ("[T]he 'written description' in the . . . specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining.") In *Johnson*, the Court of Customs and Patent Appeals held that an amendment removing from the original claims two species found in the prior art satisfies § 112, first paragraph, based on the disclosure in the specification of those two species.

Applicants submit that no new matter has been added via these amendments to the claims.

Written Description Rejection

Claims 8-13 have been rejected under 35 U.S.C. § 112, first paragraph, as containing "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time that the application was filed, had possession of the claimed invention." (Paper No. 20081029 at 3.) The Office has taken the position that "[m]ere indistinct terms (such as hydrophilic group, chemical bond, alkyl, aryl, several hydroxyl alkyl groups containing phosphate groups, etc.

throughout the claims), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms." (*Id.*) Applicants respectfully traverse.

As is well accepted, there is a strong presumption that an adequate written description of the claimed invention is present in an application as filed. See *In re Werthheim*, 191 U.S.P.Q. 90, 97 (CCPA 1976) and M.P.E.P. § 2163(II)(A). Further, an applicant may show possession of the claimed invention by describing it using descriptive means such as, for example, words, structures, figures, diagrams and formulas. See M.P.E.P. § 2163(I) citing *Lockwood v. American Airlines, Inc.*, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997).

Contrary to the Examiner's allegation, the claimed compound is not claimed in purely function terms. In fact, the claimed composition is claimed almost exclusively in structural terms. While the preamble recites an oral hygiene composition, the claimed composition is recited to comprise "a polyphosphonate compound" having an explicitly recited chemical formula, with clearly defined substituents. Moreover, there is nothing indistinct about any of the terms used to describe the substituents. One of skill in the art would have no difficulty understanding what a chemical bond or alkyl group, for example, include as used in the claim.

Moreover, contrary to the Examiner's position, there is simply no requirement that written description for a claimed genus must be satisfied by disclosure of representative number of species. Rather, disclosure of a representative number of species is merely one way to satisfy the written description requirement. (See M.P.E.P. § 2163(II)(A)(3)(a) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species . . . .") In short, an applicant may satisfy the

written description requirement with any description that provides sufficient detail to one of skill in the art to show that the applicant was in possession of the claimed invention. (See M.P.E.P. § 2163(I).) A representative number of species is but one of these ways.

The present claims clearly satisfy the written description requirement. The claimed composition is recited to contain a compound defined by a complete, explicit chemical structure reciting common and clearly understood and defined chemical substituents. In view of this detailed structural description, Applicants respectfully submit that the claimed invention is described in terms sufficient to demonstrate that, at the time of invention, they were in possession of the claimed invention. Nothing more is required. Withdrawal of the rejection is respectfully requested.

Enablement Rejection

Claims 8-13 were rejected under 35 U.S.C. § 112, first paragraph, on the asserted grounds that the specification is not enabling. (Paper No. 20081029 at 5.) In making the rejection, the Examiner concluded that "it would require an undue amount of experimentation to make the invention of the claims with various substituents, or for using them [in] oral hygiene products." (*Id.* at 11.) Applicants respectfully traverse.

The "analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention" without undue experimentation. M.P.E.P. § 2164.01. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is

necessary, it is undue. *In re Angstadt*, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976).

"There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue.'" M.P.E.P. § 2164.01. The controlling law in this issue is *In re Wands*, which contains an exemplary list of such factors, including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

As *Wands* makes clear, "[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis **must consider all the evidence related to each of these factors**, and any conclusion of nonenablement must be based on the evidence as a whole." M.P.E.P. § 2164.01(a) citing *Wands*, 8 U.S.P.Q.2d at 1404, 1407. To make out a rejection for lack of enablement, the Examiner must demonstrate, based on evidence of each of the above factors, that the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. See *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993).

The rejection simply does not contain the required analysis of the evidence pertaining to the *Wands* factors. The rejection consists of a number of conclusions and lacks evidence to support these conclusions. These conclusions include:

A) "It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity,"

B) The "level of unpredictability in the art is very high,"

C) The "level of skill [in the art] is very high,"

D) "In the absence of guidance provided in the specification, one skilled in the art would undergo undue experimentation while practicing the invention,"

E) "There is absolutely no predictability even in view of the seeming high level of skill in the art,"

F) "[I]t would require an undue amount of experimentation to make the invention of the claims with various substituents, or for using them [in] oral hygiene products,"

G) "[I]t is not seen where the instant specification enables the ordinary artisan to make and/or use the instantly claimed invention." (Paper No. 2001029 at 6-11.)

These conclusions, without more, do not provide the **evidence** required to demonstrate that undue experimentation is required to practice the claimed invention. In addition, the section entitled "The amount of direction or guidance and the presence or absence of working examples" does not actually discuss Applicants' specification. Instead, the section includes numerous case citations, which appear to state the legal standard for analyzing this *Wands* factor.

In short, the analysis and evidence required by *Wands* has not been provided in the instant rejection. Accordingly, the rejection does not present a *prima facie* case for lack of

enablement. Withdrawal of the rejection is respectfully requested.

35 U.S.C. § 112, Second Paragraph

Claims 8-13 have been rejected as indefinite. In making the rejection, the Examiner asserted only that "Claim 5 recites the limitation[s] 'one or several hydroxyl' . . . [and] 'protected by a group that becomes a hydrophilic group again after a biological hydrolysis' . . . ." which are vague and indefinite. (Paper No. 20081029 at 13 (emphasis added).) Applicants respectfully traverse.

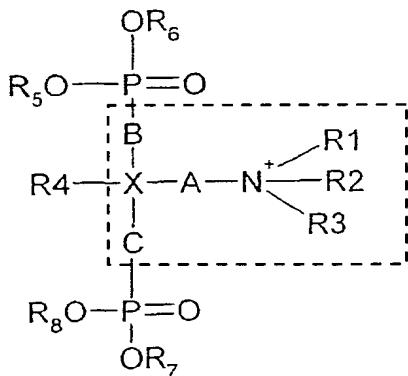
Claim 5 has been withdrawn from consideration, and is therefore, not currently under examination. Moreover, claims 8-13 do not contain the phrases to which the Examiner has objected. Accordingly, it appears that the rejection has been made in error. Applicants submit that claims 8-13 fully comply with the requirements of 35 U.S.C. § 112, second paragraph. Withdrawal is respectfully requested.

35 U.S.C. § 103

Claims 8-13 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Aymard, et al., EP 0 216 681 ("Aymard"). (Paper No. 20081029 at 13.) The Examiner has alleged that Aymard teaches a process for preparing cationic dispersing agents . . . by the reaction of a compound containing OH and phosphono groups with a compound containing a quaternary N and a group reactive with phosphono groups, . . . [which] are useful in the paper, textile and coating industries." (*Id.*) The Examiner has determined that "it would have been obvious . . . to utilize the cationic dispersant in oral preparations and come to the claimed invention with the reasonable expectation of success." (*Id.* at 15.) Applicants respectfully traverse.

Aymard's contribution to the field is a cationic dispersant compound in which a phosphonic acid group is bonded to a quaternary nitrogen-containing substituent. The claimed compositions contain a compound in which a quaternary nitrogen-substituent is bonded to a carbon connecting phosphonic acid groups. To make the modification suggested by the Examiner requires ignoring the explicit teachings of Aymard. Accordingly, the rejection does not present a *prima facie* case for obviousness.

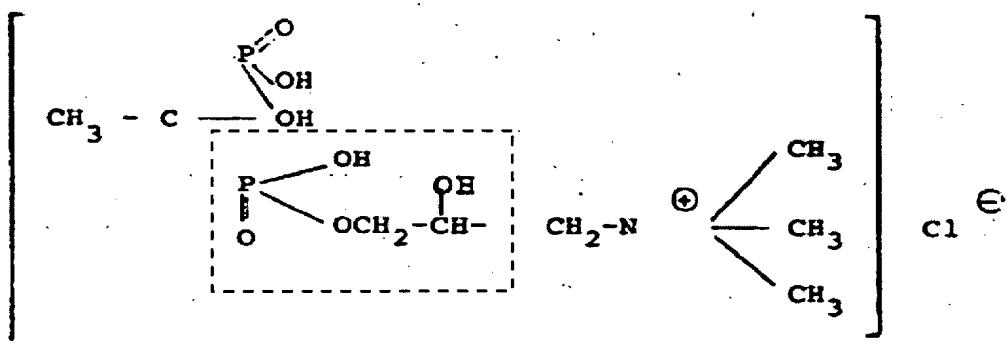
The compounds of the claimed compositions have a quaternary nitrogen-substituent bonded to a carbon connecting two or more phosphonic acid groups (X)<sup>1</sup> (as shown in the dashed box below) :



(1)

In contrast, Aymard teaches that its compositions are formed by the condensation of a phosphonated compound containing free phosphonic acid groups and a hydroxyl group with a compound containing a quaternary nitrogen atom and a group which reacts with a phosphonic acid group of the phosphonated compound. (Abstract.) The condensation reaction of the phosphonic acid group must produce a compound in which one of the phosphonic

acid groups is bonded to the quaternary nitrogen-containing substituent. Indeed, the single embodiment taught by Aymard has exactly this chemical structure (as shown in the dashed box below):



(Page 7, line 13.)

Thus, compounds made by the method taught by Aymard cannot be the claimed compounds. Likewise, the claimed compounds are not those taught by and cannot be made by the method of Aymard.

Accordingly, Aymard teaches away from the claimed compositions. *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1381, 83 U.S.P.Q.2d 1746, 1751 (Fed. Cir. 2007) (a "reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant."). To do as suggested by the Examiner, one of skill in the art would have had to essentially discard Aymard's contribution to the field, and instead use a different compound, which may or may not have been a cationic dispersant.

In essence, the Examiner has presumed that one of ordinary skill in the art would have dismantled Aymard's invention to arrive at the claimed invention. However, the routinist in the art is an objective legal construct, who is

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<sup>1</sup> Claim 8 has been amended to recite that X is a carbon atom and B and C are chemical bonds. Accordingly, in the claimed compositions, the free phosphonic acid groups are directly bonded to carbon atom X.

presumed to think along conventional lines, without undertaking to innovate, whether by systematic research or by extraordinary insights. See *Life Technologies Inc. v. Clontech Lab, Inc.*, 56 U.S.P.Q.2d 1186, 1190 (Fed. Cir. 2000) (quoting *Standard Oil Co. v. American Cyanamid Co.*, 227 U.S.P.Q. 293, 297 (Fed. Cir. 1985)).

Accordingly, one of skill in the art would have had no rationale to modify the compositions and method of Aymard, at least in the manner alleged in the Office Action. Withdrawal of the rejection is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he/she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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